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#14
10/9/03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Batra et al.

Serial No.: 09/894,921

Docket No.: 20243CA

Filed: June 28, 2001

For: "COMPRESSED TABLET FORMULATION"

Examiner: Sharareh, Shahnam

Art Unit: 1617

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MUNIR ALWAN HUSSAIN UNDER 37 C.F.R. § 1.132

Sir:

I, Munir Alwan Hussain, hereby declare and say:

1. I am a United States citizen, and I reside at 136 Belle Glades Lane, Belle Mead, NJ 08502

2. I graduated in 1983 from the University of Kentucky located in Lexington, Kentucky with a Ph.D in Pharmaceutical Sciences.

3. I have been employed since 2002 by Bristol-Myers Squibb Pharma in New Brunswick, New Jersey, where I am currently a Senior Research Fellow. The focus of my work is drug product formulation development of different dosage forms, providing process for clinical supplies manufacture and scale-up, particle engineering/solublization technologies, and drug delivery through alternate delivery routes. I was previously employed by Du Pont Pharmaceuticals Company in Wilmington, Delaware, where I was a Director in charge of the department of formulation development of oral solid, oral liquid, and injectable dosage forms.

4. I attach a copy of my biography and curriculum vitae as Exhibit 1, which provide further information on my educational background and work experience, and includes a list of my publications.

5. I have read and understand the subject application, which is directed to compressed tablet formulations for efavirenz. I have also read and understand Makooi (US 6,238,695 B1), Remington: The Science and Practice of Pharmacy, 19th edition, pp. 1616-1620 ("Remington"), and Christ (US 5,874,430), each of which has been cited by the Examiner during the examination of the subject application.

6. The subject application claims a compressed efavirenz tablet containing from about 1% to about 5% by weight superdisintegrant, whereas Makooi teaches efavirenz tablets and capsules containing 10 wt.% or more of a superdisintegrant.

7. I report here the results of bioavailability studies conducted using tablets prepared in accordance with the claimed invention and using tablets and capsules prepared in accordance with the teachings of Makooi. All of the studies were conducted at DuPont Pharmaceuticals Company (since acquired and now part of Bristol-Myers Squibb Pharma Co.) using tablets and capsules. The tablets used in the studies were prepared either by me directly or prepared under my supervision. Commercial capsules obtained from the factory were used in all of the studies except Study B, which used capsules prepared under my supervision and which had the same composition as the commercial capsules.

8. The studies described below were bioequivalency studies that were part of the effort to develop an efavirenz compressed tablet that was bioequivalent to the commercial capsule formulation of efavirenz. A tablet and capsule would have bioequivalence if the tablet has the same bioavailability as the capsule. Bioavailability refers here to the degree to which the active ingredient becomes available in the bloodstream, and is determined by measuring certain pharmacokinetic (PK) parameters, including in particular AUC (= area under the curve of plasma concentration v. time) and C_{max} (= maximum plasma concentration). Means and standard deviations for AUC and C_{max} are given below as part of the description of each of the studies. In these studies, a tablet formulation was considered bioequivalent to the commercial capsule formulation if the PK parameters were the same within 80-125% limits for the 90% CI. Thus, a statement below that a tablet formulation had a bioavailability more or less than that of the capsule means that one or more of the PK parameters for the tablet did not meet the 80-125% criterion at 90% CI.

9. Study A was a single-dose PK study in fasted humans, in which AUC and C_{max} were determined for 300 mg and 600 mg tablets containing 12 wt.% sodium starch glycolate (SSG) and 60 wt.% efavirenz and for 200 mg commercial efavirenz capsules (SUSTIVA® capsules). The commercial capsules, which contain 39 wt.% efavirenz and 35 wt.% SSG, are manufactured in accordance with the teachings of Makooi (see, e.g., Example 1 in column 6). The commercial capsules contain the same ingredients as listed in the table in Example 1 of Makooi (see column 6, lines 37-47), in the same proportions, but double the amounts. The coated tablets were also prepared in accordance with the teachings of Makooi (see, e.g., Example 3 in column 7). The core composition (i.e., excluding the film coating) of the 300 mg tablets was as follows:

Ingredient	Amount per Tablet (mg)
efavirenz	300
SSG	60
microcrystalline cellulose	123
Na lauryl sulfate	12
magnesium stearate	5

Water employed in the preparation of the tablet was removed during drying.

The 600 mg coated tablets had the same core ingredients in the same proportions but double the amounts.

10. Study A was conducted as a two-way, crossover study employing 12 healthy subjects under fasting conditions, wherein all twelve subjects took 2 x 300 mg tablets and 3 x 200 capsules, and also took a 1 x 600 mg tablet and 3 x 200 mg capsules. The results obtained in Study A are as follows, wherein the tablets were less bioavailable than the capsules:

	Tablet	Capsule
Run 1 (12 subjects):		
Dosage	2 x 300 mg	3 x 200 mg
AUC (μM•h)	273 ± 85	361 ± 111
C_{max} (μM)	4.03 ± 1.56	7.72 ± 2.95
Run 2 (12 subjects):		
Dosage	1 x 600 mg	3 x 200 mg
AUC (μM•h)	277 ± 95	337 ± 72
C_{max} (μM)	5.14 ± 1.51	7.30 ± 2.10

11. Study B was a single-dose PK study in fasted beagle dogs in which AUC and C_{max} were determined for 300 mg tablets containing 10 and 20 wt.% SSG and 50 wt.% efavirenz and for 200 mg capsules. The capsules employed in this study were prepared under my supervision. The capsules had the same composition and were prepared in the same manner as the commercial capsules (i.e., in accordance with Makooi; see paragraph 9 above). The coated tablets were also prepared in accordance with the teachings of Makooi (see paragraph 9 above). The core composition of the 10% SSG tablets was as follows:

Ingredient	Amount per Tablet (mg)
efavirenz	300
SSG	60
microcrystalline cellulose	120
Na lauryl sulfate	12
lactose monohydrate	102
magnesium stearate	6

Water employed in the preparation of the tablet was removed during drying.

The 20% SSG tablets contained the same ingredients in the same amounts, except that the amounts of SSG and lactose monohydrate were adjusted to give 20 wt.% SSG.

12. Study B was conducted as a three-way, crossover study in which each of six dogs took 2 x 300 mg 10% SSG tablets, 2 x 300 mg 20% SSG tablets, and 3 x 200 mg capsules under fasting conditions. The results obtained in Study B are as follows, wherein the tablets were less bioavailable than the capsules:

	10% SSG Tablet	20% SSG Tablet	Capsule
(6 dogs)			
Dosage	1 x 300 mg	1 x 300 mg	3 x 200 mg
AUC (μM)	4.51 ± 1.78	3.23 ± 0.93	5.12 ± 0.90
C_{max} (μM-hr)	0.76 ± 0.22	0.61 ± 0.16	0.84 ± 0.20

13. Study C was a single-dose PK study in fasted humans in which AUC and C_{max} were determined for 300 mg tablets containing 5 wt.% croscarmellose (CROS) and 50 wt.% efavirenz and for 200 mg capsules. The capsules were commercial capsules (see paragraph 9 above for further description of their composition and preparation). The coated tablets were prepared in accordance with the process described in the subject application (see, e.g., the process set forth on page 5 of the subject application). The core composition of the tablets was as follows:

Ingredient	Amount per Tablet (mg)
efavirenz	300
croscarmellose Na	30
microcrystalline cellulose	120
Na lauryl sulfate	6
hydroxypropyl cellulose	19.2
lactose, monohydrate	118.8
magnesium stearate	6

Water employed in the preparation of the tablet was removed during drying.

14. Study C was an open-label, randomized, two-period crossover study in which twelve subjects received single 600 mg oral doses of each of the formulations under fasting conditions. The results obtained in Study C are as follows, wherein the PK values of the tablet were equivalent to those of the capsule:

	Tablet	Capsule
(12 subjects)		
Dosage	2 x 300 mg	3 x 200 mg
AUC (μM•h)	317.9 ± 91.4	329.4 ± 86.2
C_{max} (μM)	8.19 ± 2.15	8.34 ± 2.63

15. Study D was a single-dose PK study in fasted humans similar to Study C, except that a larger subject population was employed and 600 mg tablets containing 5 wt.% CROS were tested in addition to 300 mg tablets containing 5 wt.% CROS. The 600 mg tablets had the same core ingredients as the 300 mg tablets, wherein the amount of each core ingredient in the 600 mg tablet was twice that in the 300 mg tablet (see paragraph 13). The tablets used in Study D were prepared in the same manner as the tablets in Study C. The capsules were commercial capsules.

16. Study D was an open-label, randomized, three-period crossover study in which 28 subjects received single 600 mg doses of each of the formulations under fasting conditions. The results obtained in Study D are as follows, wherein the AUC values of the tablets and capsules were equivalent and the C_{max} values of the tablets were higher than that of the capsules:

	300 mg Tablet	600 mg Tablet	Capsule
(28 subjects)			
Dosage	2 x 300 mg	1 x 600 mg	3 x 200 mg
AUC (μM)	463.18 ± 178.58	451.41 ± 183.99	421.85 ± 175.47
C_{max} (μM-hr)	9.51 ± 2.21	9.17 ± 2.63	7.58 ± 2.21

17. Study E was a single-dose PK study in fasted humans analogous to Study D, wherein 300 mg and 600 mg tablets containing 4 wt.% CROS were tested. The 300 mg tablets had the same ingredients in the same amounts as the 300 mg tablets employed in Study C (see paragraph 15), except that the amount of CROS in Study E was 24 mg (v. 30 mg) and the amount of lactose monohydrate was 124.8 mg (v. 118.8 mg). The 600 mg tablets were essentially the same as the 300 mg tablets, except that the ingredient amounts were doubled. The tablets used in Study E were prepared in the same manner as the tablets in Study C. The capsules were commercial capsules.

18. Like Study D, Study E was an open-label, randomized, three-period crossover study in which 28 subjects received single 600 mg doses of each of the formulations. The results

obtained in Study E are as follows, wherein the PK values of the tablets and capsules were equivalent:

	300 mg Tablet	600 mg Tablet	Capsule
(21 subjects)			
Dosage	2 x 300 mg	1 x 600 mg	3 x 200 mg
AUC (μM)	363.28 ± 124.75	374.24 ± 121.73	359.01 ± 118.56
C_{max} (μM-hr)	7.62 ± 2.26	8.06 ± 1.95	7.50 ± 2.81

19. Summarizing these studies, efavirenz tablets containing 10 wt.% or more of a superdisintegrant (Studies A and B) were found to be less bioavailable than the commercial capsules, whereas tablets containing 5 wt.% or less of a superdisintegrant (Studies C, D and E) were found to have the same or better bioavailability than the commercial capsules. This result is unexpected; i.e., there is no suggestion in Makooi that efavirenz tablets containing 5 wt.% or less superdisintegrant would have a bioavailability the same as or better than that of the commercial capsules, and also significantly better than comparable tablets containing more than 10 wt.% superdisintegrant.

20. It is further noted that there is typically a market preference for tablets over capsules, in part because tablets of equal or greater dose are usually smaller and easier to swallow. Absent the development of a bioequivalent tablet, however, a full scale clinical trial with a non-equivalent tablet is required to demonstrate the tablet's safety and efficacy, which of course can substantially delay approval and launch. The claimed invention resulted in the development of an FDA-approved bioequivalent tablet without the need for a full scale clinical trial, a benefit not achieved via the Makooi invention.

21. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the subject application or any patent issuing therefrom.

October - 1st - 2003
Date

Munir Alwan Hussain
Munir Alwan Hussain

Munir A. Hussain, Ph.D.

Munir Hussain is a Senior Research Fellow at Bristol-Myers Squibb Company, New Brunswick, New Jersey. He received his B.S. in pharmacy from the University of Baghdad, Iraq and his Ph.D. in pharmaceutical sciences from the University of Kentucky in 1983. He holds adjunct professor appointments at the School of Pharmacy, Duquesne University; College of Pharmacy, University of Kentucky; School of Pharmacy, Temple University; College of Pharmacy, University of Tennessee; and serves as a board member, College of Pharmacy and Pharmaceutical Sciences, Florida A&M University. He serves as a member on many graduate students'research committees and a member of the PQRI Drug Specifications Working Group. He is a member of the editorial boards of the journal of Pharmaceutical Development and Technology and AAPS PharmSciTech. He is the author of over 80 refereed publications in different areas of pharmaceutical sciences, 90 abstracts/national and international seminars, and 11 issued patents. He is a Fellow of the American Association of Pharmaceutical Scientists (1993). His research interests include drug delivery, preformulation, mechanisms of degradation and stabilizations of drugs, and formulation development/optimization and scale-up.

CURRICULUM VITAE

General Information:

Home address: 136 Belle Glades LN
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Ph: (908) 359-8789

Marital Status: Married, two children

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P.O. Box 191
New Brunswick, NJ 08903-0191
Ph: (732) 519-3272
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Education:

1982-1983	Postdoctoral fellow College of Pharmacy University of Kentucky Lexington, Kentucky Dr. Anwar Hussain
1978-1983	Ph.D. Pharmaceutical Sciences University of Kentucky Lexington, Kentucky Dr. George Digenis, Advisor **Thesis:** Development of Methodology for Preparation of ^{11}C-Labeled Phenethylamine-type Compounds and Studies on the Effect of Amphetamine on Brain Efflux of Radiolabeled Phenethylamine.
1970-1977	Retail Pharmacist, Iraq
1970	B.S. Pharmacy, College of Pharmacy University of Baghdad, Iraq

Summary of Research Interests and Experiences:

Research activities included optimization of drug absorption and novel drug delivery systems. Examples of activities: designing, synthesizing and evaluating prodrugs to improve oral bioavailability; novel oral sustained release delivery systems; evaluating the feasibility of transmucosal delivery; solubilization of drugs for parenteral administration; research activities related to oral and transmucosal peptide delivery; introduced the concept of using mechanism based reversible peptidase inhibitors to improve stability of peptide drugs during their absorption through different mucosae; and interaction and coordination of activities with outside delivery technologies for inhouse drugs.

Formulation development of oral (solid and liquid) and parenteral (solution and lyophilized) dosage forms including manufacturing of clinical supplies (inhouse and at contract sites), and technology transfer to manufacturing sites.

Professional Employment:

11/01- present	Senior Research Fellow, Pharmaceutics R&D, Pharmaceutical Research Institute, Bristol-Myers Squibb Company, P.O. Box 191, New Brunswick, NJ 08903-0191 Responsible for the organization and operation of formulation development of different dosage forms, providing process for clinical supplies manufacture and scale-up; particle engineering/solubilization technologies; and drug delivey through alternate delivery routes.
2/97-11/01	Director, Formulation Development, DuPont Pharmaceuticals Company, Wilmington, DE 19880-0400 Responsible for the organization and operation of formulation development of oral solid, oral liquid, injectable, liquid and lyophilized, dosage forms. Providing process for clinical supplies manufacture and commercialization. Heading Technology Transfer Team and organize activities with different groups in the company to assure product approval.
5/94-2/97	Director, Basic Pharmaceutics and Liquids Formulation Development, DuPont Merck Pharmaceutical Company, Wilmington, DE 19880-0400
1/94-5/94	Associate Director, Basic Pharmaceutics and Liquids Formulation Development, DuPont Merck Pharmaceutical Company, Wilmington, DE 19880

Responsible for research, organization (25 scientists) and operation for all activities related to discovery support, preformulation, drug delivery systems (oral, nasal, buccal, transdermal and rectal), techniques to evaluate G.I permeability such the in vitro intestinal techniques and the Caco-2 cell technique. Formulation of Parenteral (lyophilized/liquid) and other non-injectable liquid formulations and providing process for clinical supplies manufacture and commercialization. Responsible for Pharmacy submission section regarding physical-chemical properties. Responsible for evaluation and coordination of outside technologies. Worked very closely with Analytical R&D in solving problems and identifying degradants in dosage forms and providing solutions to stabilize formulations when needed.

11/91-1/94 Associate Director, Basic Pharmaceutics, DuPont Merck Pharmaceutical Company, Wilmington, DE 19880-0400

05/90-11/91 Senior Group Leader, Basic Pharmaceutics, DuPont Merck Pharmaceutical Company, Wilmington, DE 19880-0400

01/89 -5/90 Group Leader, Basic Pharmaceutics, DuPont Company, Wilmington, DE 19880-0400

Responsible for the organization (15 scientists) and operation of all discovery support with regard to physical-chemical evaluations including providing early formulations for predevelopment compounds. Responsible for identifying the correct salt and crystal form, performing initial stability studies on active drug substance and in presence of excipients, identifying the thermal behavior of drug substance. Responsible for the operation of the drug delivery systems group identifying problems with oral absorption using animal models and intestinal segments in vitro, in addition to other non-oral delivery routes (nasal, buccal, rectal, transdermal).
Responsible for all preformulation and physical-chemical data that go into the CMC. Headed a team from Medical, Marketing and Business Strategy to identify line extensions. This group came up with two line extensions that resulted in a new use for an old drug and a combination formulation that went into Phase III clinical trials.

06/88-12/88 Group Leader, Drug Delivery Systems, DuPont Company, Wilmington, DE 19880-0400

Responsible for the organization (10 scientists) and operation of the Drug Delivery Systems Group. This group came up with a transdermal delivery system for an old drug. Oral sustained

release dosage form technologies were developed. Developed in-house technologies to examine nasal delivery and provide nasal formulations for non-peptides, peptidomimetics and small peptides. These activities resulted in the issuance of two patents. This group was also responsible for identifying oral absorption problems and providing solutions for the problems.

06/87-06/88 Senior Research Pharmacist, Drug Delivery Systems, DuPont Company, Wilmington, DE 19880-0400

12/83-1987 Research Pharmacist, Drug Delivery Systems, DuPont Co., Wilmington, DE 19880-0400

Responsible for a group (4 scientists) to conduct research in the areas of prodrug design, synthesis and evaluation, buccal, transdermal and nasal delivery systems. Designed bitterless prodrugs for buccal delivery and prodrugs for improving oral bioavailability that resulted in the issuance of two patents. Provided solubilization techniques for parenteral formulation of insoluble drugs. Solved problems with particulate matters in parenteral dosage forms.

Academic and Professional Honors:

- AAPS Fellows Selection Committee, Pharmaceutical Technology Section, 2003.
- AAPS Fellows Selection Committee, Pharmaceutical Technology Section, 2002.
- Product Quality Research Institute (PQRI) Drug Substance Specifications Working Group Committee Member, 2001.
- AAPS Fellows Selection Committee, Pharmaceutical Technology Section, 2001.
- Reviewer for the State of New Jersey Commission on Science and Technology, 2000 - present.
- Editorial Advisory Board Member of the Journal of AAPS PharmSciTech, 2000 - present.
- Adjunct Professor Appointment, Department of Pharmaceutical Sciences, College of Pharmacy, University of Tennessee, 2000 - present.
- AAPS Fellows Selection Committee, 1998.
- AAPS Fellows Selection Committee, Pharmaceutics and Drug Delivery Section, 1998.

- Advisory Committee Member, Center For Pharmaceutical Science & Technology, College of Pharmacy, University of Kentucky, 1998 - present.

- Adjunct Professor of Pharmaceutics, School of Pharmacy, Temple University, 1996 – present.

- Editorial Advisory Board Member of the Journal of Pharmaceutical Development and Technology, 1996 - present.

- Chairman of the NIH, National Cancer Institute, Formulation Grant Review Panel, 1996.

- Adjunct Associate Professor Appointment, Department of Pharmaceutical Chemistry and Pharmaceutics, School of Pharmacy, DuQuesne University, 1994 – present

- Elected as American Association of Pharmaceutical Scientists Fellow, 1993.

- Board Member, College of Pharmacy and Pharmaceutical Sciences, Florida Agricultural and Mechanical University, 1992 - present.

- Assistant Professor Appointment, College of Pharmacy, University of Kentucky, 1989 – present.

Associations: The Rho Chi Pharmaceutical Honor Society
American Pharmaceutical Association
American Association of Pharmaceutical Sciences
Parenteral Drug Association

Appointments on Graduate students Advisory Committees:

- *Dr. Sherif Badawy, 1994, School of Pharmacy, DuQuesne University*
- *Dr. Abeer AlGananeem, 1997, College of Pharmacy, University of Kentucky*
- *Dr. Thomas Durig, 1998, School of Pharmacy, Temple University*
- *Dr. Viness Pillay, 1998, School of Pharmacy, Temple University*
- *Mr. Rahmat Talukder, 2002, School of Pharmacy, Temple University*
- *Mr. Yunqi Wu, 2003, School of Pharmacy, Temple University*

Publications:

1) Munir A. Hussain, James E. Chaney, George A. Digenis and W. John Layton, Mechanistic Study on Exchange Between Labeled Cyanide and Nitriles, J. Labeled Compd. and Radiopharmaceuticals, 22, 983 (1985).

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5) Munir A. Hussain, Bruce J. Aungst, Gilbert Lam and Eli Shefter, Phenylpropanolamine Pharmacokinetics in Dogs after Intravenous, Oral, and Oral Controlled-Release Doses, Biopharm. Drug. Disp., 8, 497 (1987).

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8) Munir A. Hussain, Andrew T. Chiu, William A. Price, Pieter B. Timmermans and Eli Shefter, Antihypertensive Activity of 2[(2-Hydroxyphenyl)amino]-4(3H)-quinazolinone, Pharm. Res., 5, 242 (1988).

9) Munir A. Hussain, Bruce J. Aungst, Christopher A. Koval and Eli Shefter, Improved Buccal Delivery of Opioid Analgesics and Antagonists with Bitterless Prodrugs, Pharm. Res., 5, 615 (1988).

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14) Bruce J. Aungst, Judy A. Blake and Munir A. Hussain, Contributions of Drug Solubilization, Partitioning, Barrier Disruption, and Solvent Permeation to the Enhancement of Skin Permeation of Various Compounds with Fatty Acids and Amines, Pharm. Res. 7, 712 (1990).

15) Munir A. Hussain, Christopher A. Koval, Ashok B. Shenvi and Bruce J. Aungst, Recovery of the Rat Nasal Mucosa from the Effects of Aminopeptidase Inhibitors, J. Pharm. Sci., 79, 398 (1990).

16) Munir A. Hussain, Christopher A. Koval, Ashok B. Shenvi and Bruce J. Aungst, An Aminoboronic Acid Derivative Inhibits Thymopentin Metabolism by Mucosal Membrane Aminopeptidases, Life Sciences, 47 (3), 227 (1990).

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22) Munir A. Hussain and Joseph A. Mollica, Intranasal Absorption of Physostigmine and Arecoline, J. Pharm. Sci., 80, 750 (1991).

23) Bruce J. Aungst, Judy A. Blake and Munir A. Hussain, An In Vivo Evaluation of Metabolism and Poor Membrane Permeation Impeding Intestinal Absorption of Leucine Enkephalin, and Methods to Increase Absorption, J. Pharm. Exp. Ther., 259, 139 (1991).

24) Munir A. Hussain, Robert Knabb, Bruce J. Aungst, and Charles Kettner, Anticoagulant Activity of a Peptide Boronic Acid Thrombin Inhibitor by Various Routes of Administration in Rats, Peptides, 12, 1153 (1991).

25) Michael B. Maurin, Rodney D. Vickery, William M. Briant III, and Munir A. Hussain, Physicochemical Properties of the Novel Heteropolyanion Antiviral Hexapotassium-α-Vanado-II-Tungstoborate (DuP 925), Pharm. Res., 9, 570 (1992).

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9) Iontophoretic Delivery of Integrin Inhibitors, M. A. Hussain, and A. J. Repta. U.S. Patent # 6,185,453 B1 issued February 6, 2001.

10) Integrin Inhibitor Prodrugs, P.K. Jadhav, D.G. Batt, M.A. Hussain, W.J. Pitts, A.J. Repta, U.S. Patent # 6,214,834 B1 issued April 10, 2001.

11) Use of Polyalkylamine Polymers in Controlled Release Devices, Munir A. Hussain, and Arnold J. Repta, U.S. Patent Application filed February, 2001.

12) Efavirenz Tablet Formulation Having Unique Biopharmaceutical Characteristics, Munir A. Hussain and Zhihui Gao, U.S. Patent Application filed February, 2002.

Invited Lectures and Symposia:

May 1990, Transmucosal Absorption of Peptides, at the Jordanian Pharmaceutical Association Meeting, Amman, Jordan.

May 1991, The Use of Peptidase Inhibitors to Stabilize Peptide Drugs During Their Intranasal Absorption, at the AAPS Midwest Regional Meeting.

April 1992, Nasal Peptide Delivery and the Use of Peptidase Inhibitors, at Drug Delivery of Biopharmaceuticals III Conference, San Diego, CA.

September 1993, Transmucosal Peptide Delivery, at School of Pharmacy, Duquesne University.

March 1995, Biodegradable and Non-biodegradable Implantable Delivery Systems, College of Pharmacy, University of Kentucky.

March 1995, Buccal Drug Delivery, College of Pharmacy, University of Kentucky.

March 1995, Peptide Delivery, College of Pharmacy, University of Kentucky.

April 1995, invited speaker, Identification and Characterization of Impurities and Degradation Products Associated with Manufacture of Drug Product, at the AAPS Workshop on Impurities in Drug Substances and Products: Issues, Strategies and New Technologies, April 3-4, 1995, Arlington, VA.

November 1995, invited speaker, Peptide Delivery, at The PDA meeting Nov. 13-15, 1995, Boston, MA.

March 1996, invited speaker, Nasal Peptide Delivery, at the Twenty-Ninth Annual Higuchi Research Seminar, Lake Ozark, Missouri.

March 1996, invited speaker, Peptide Drug Delivery, School of Pharmacy, Temple University.

August 1996, organizer and chairman, Symposium on Drug Delivery, Preformulation and Formulation, at the 1996 Conference on Science and Technology in conjunction with the 1996 International Conference on Food Science and Technology and the 27th Annual Meeting of the Fine Particle Society, August 6-8,1996, Chicago, Illinois.

August 1996, invited speaker, Nasal Peptide Delivery, at the Symposium on Drug Delivery, Preformulation and Formulation, at the 1996 Conference on Science and Technology in conjunction with the 1996 International Conference on Food Science and Technology and the 27th Annual Meeting of the Fine Particle Society, August 6-8, 1996, Chicago, Illinois.

September 1996, invited speaker, Nasal Peptide Delivery: The Enzymatic Barrier, at the 8th International Pharmaceutical Technology Symposium, September 9-11, 1996, Ankara, Turkey.

December 1996, invited speaker, Systemic Drug Delivery Via the Mucous Membranes of the Oral Cavity, School of Pharmacy, Temple University.

December 1996, invited speaker, Salt Selection in Pharmaceutical Development, School of Pharmacy, Temple University.

February 1997, Transdermal Drug Delivery, College of Pharmacy, University of Kentucky.

February 1997, Nasal and Buccal Drug Delivery, College of Pharmacy, University of Kentucky.

July 1997, invited speaker, Nasal Delivery as an Alternative for Peptides, 1997 Colorado Biopharmaceutical Delivery Conference, July 24-26, 1997, Breckenridge, Colorado.

November 1997, invited speaker, Mechanisms, Identification and Characterization of Degradants in Drug Products, School of Pharmacy, Temple University.

February 1998, Nasal Drug Delivery as an Alternative Route, College of Pharmacy, University of Kentucky.

October 1998, invited speaker, Preformulation Testing and Techniques, School of Pharmacy, Temple University.

October 1998, invited speaker at the 1998 Postgraduate Course in Tablet Technology (Formulation, Processing, Testing and FDA Requirements), The University of Tennessee, Memphis, College of Pharmacy.

February 1999, Systemic Drug Delivery Through the Nasal Route, College of Pharmacy, University of Kentucky.

February 1999, Systemic Drug Delivery Through the Buccal and Sublingual Mucosae, College of Pharmacy, University of Kentucky.

March 1999, invited speaker at the 1999 Postgraduate Course in Tablet Technology (Formulation, Processing, Testing and FDA Requirements), The University of Tennessee, Memphis, College of Pharmacy.

April 1999, invited speaker, The Nasal Route as an Alternative for Systemic Drug Delivery, at the 1999 Second Annual Northeast Regional Discussion Group meeting on Alternative Routes for Systemic Drug Delivery, Rocky Hill, Connecticut.

February 2000, Drug Delivery Through the Nasal and Oral Mucosal Routes, College of Pharmacy, University of Kentucky.

June 2000, invited speaker at the Postgraduate Course in Tablet Technology (Formulation, Processing, Testing and FDA Requirements), The University of Tennessee, Memphis, College of Pharmacy.

February 2001, Systemic Drug Delivery Through the Buccal and Sublingual Mucosae, College of Pharmacy, University of Kentucky.

September 2001, Drug Solubility and Solubilization Methods, College of Pharmacy, University of Kentucky.

September 2001, Preformulation and Early Drug Formulation Development, College of Pharmacy, University of Kentucky.

March 2003, invited speaker at the Postgraduate Course in Tablet Technology (Formulation, Processing, Testing and FDA Requirements), The University of Tennessee, Memphis, College of Pharmacy.